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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,551	09/27/2001	Muthiah Manoharan	ISIS-4847	3873

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/965,551	Applicant(s) MANOHARAN, MUTHIAH	
	Examiner Konstantina Katcheves	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30 and 52-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30, 52-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 28-30 and 52-69 are pending in the present application. This Office action is in response to Applicant's amendment and remarks filed 22 October 2003.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 October 2003 has been entered.

Response to Arguments

Claims 28-30 and 52-69 stand rejected for lack of enablement under 35 U.S.C. 112, first paragraph for the reason already of record and those set forth below. Applicant requests reconsideration of two points in the remarks dated 22 October 2003. Applicant has not provided any new un rebutted arguments. However, for purposes of clarification Applicant's remarks addressed for below.

First, Applicant points to a press release dated 10 September 2003 wherein Genta Incorporated announces results from its phase III clinical trials of the antisense drug, Genasense™ to establish that antisense technology does indeed work *in vivo* to refute the Examiner's position that antisense is a highly unpredictable art. In addition to the reason set forth in the Advisory Action mailed 20 August 2003. Applicant should note that one should

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evaluate whether the invention is enabled based on the filing date sought. According to MPEP

2164.05(a):

Whether the specification would have been enabling *as of the filing date* involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. . . . The *state of the art* for a given technology *is not static in time*. It is entirely possible that a disclosure filed on January 2, 1990, would not have been enabled. However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date. [emphasis added].

Applicant's invention receives priority to Application 09/115025, now US Patent 6,277,967 filed 14 July 1998. Therefore, assuming *arguendo* that the Genta Incorporated press release of 10 September 2003 shows that antisense therapy generally is enabled, it does not provide evidence that the invention is enabled as of the filing date sought.

Second, Applicant again emphasizes the method step of "contacting said organism." This argument has been made and previously rebutted. However, the Examiner will again address this issue. Applicant argues that the present claims are not drawn to administering a treatment or as stated in the preamble, treating an organism. Applicant attempts to steer the discussion toward the method step and argues that the ordinary and customary meaning of the term "treating" only requires the administration of a compound, i.e. the "contacting." Applicant further argues that nowhere in the claims can one find the word "treatment." Contrary to Applicant's position that the method is simply one of "contacting" a compound with an organism, Applicant's preamble states the purpose of the method: "a method of treating an organism having a disease."

Applicant should note that claims are given their broadest reasonable interpretation. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Applicant argues

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that the Examiner improperly used a medical dictionary to provide a definition of the term “treatment.” Applicant provides definitions of “to treat” from Meriam-Webster Online (Applicant’s Exhibit B), which is: “to act upon with some agent especially to improve or alter.” Applicant also provides the definition of “to treat” from Webster’s II (Applicant’s Exhibit C) which defines the verb as: “to subject to an action, process or change.” The definitions provided by Applicant are expedient for the purposes of the argument presented, however, Applicant has neglected to address that the ordinary and plain meaning of “to treat” in both dictionaries provided as Exhibit B and Exhibit C include treatment of disease. Meriam-Webster Online also defines “to treat” as: “to care for or deal with medically or surgically <*treat* a disease>.” Webster’s II also defines “to treat” as: “to give medical aid to <*treat* sick patients>.” Thus, one need not resort to medical terminology or dictionaries to interpret the claims as done so by the Examiner. Given their broadest reasonable claim interpretation and the common definitions of “to treat”, the ordinary and plain meaning of the words “treating an organism having a disease,” include treatment of an organism having a disease and administering a treatment to such an organism such that Applicant’s arguments remain untenable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
27 January 2004


REMY YUCEL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600